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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,156	11/14/2003	Mitchell I. Kirschner	718689	2373

7590 10/04/2006

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,156	KIRSCHNER ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not cite to any disclosure in the Specification which supports a nutritional supplement comprising a soft gelatin capsule comprising and essentially fatty acid and a second undefined dosage form comprising calcium. The disclosure appears to only disclose a single dosage form, i.e. soft gelatin capsule, containing the active components.

The Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The Examiner has duly considered Applicant's affidavit, however, said affidavit appears to consist entirely of conclusions that are unsupported by evidence. The affidavit states without any supporting evidence that because the application discloses the use of binders, adhesive,

disintegrants, bulking agents and plasticizers that the application must encompass the use of a tablet. However, the affidavit fails to provide any evidence which supports said conclusion and fails to provide any evidence that the soft gelatin capsule, either in the gelatin film forming the capsule or the contents contained in the cavity of the capsule, cannot contain one or more of binders, adhesive, disintegrants, bulking agents and plasticizers. It is not sufficient to show that said ingredients are included in tablets (although the affidavit does not even provide evidence of this), the affidavit must provide evidence that shows that a gelatin capsule cannot contain the same as indicated. See In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ("expert's opinion on the ultimate legal conclusion must be supported by something more than a conclusory statement"). In any case, at least one reference refutes the conclusion that ingredients that are used in tablet formulations cannot be used in soft gelatin capsule formulations. Valorose, Jr. et al. discloses a soft gelatin capsule which is filled with beads containing a mixture of a tetracycline with excipients such as microcrystalline cellulose, sodium carboxymethylcellulose, lactose or beads which are formed from coating a seed with a coating containing a tetracycline, film forming polymers and plasticizers (Column 5, lines 20-68, Column 6, Column 9, lines 37-41).

Even if the affidavit was sufficiently probative of the statements made therein, the affidavit still would not overcome the rejection. The Affidavit indicates that the inclusion of binders, adhesive, disintegrants, bulking agents and plasticizers can only mean the use of tablets is encompassed by the present invention. However, Specification does not disclose the use of tablets or that calcium is administered in a second dosage form, much less a tablet, from the essential fatty acid, in a soft gelatin shell. In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123

(CCPA 1967) ("If n- propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original); Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention .... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion"). As such, because the Affidavit does not establish that the Specification in fact provides a written description of the claimed invention, the Affidavit is not sufficient to overcome the rejection herein.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 97/04668.

WO 97/04668 expressly disclose a nutritional supplement which a soft gelatin capsule A contains evening primrose oil and soft gelatin capsule B contains calcium falling within the scope of applicant's claims (Page 14, lines 20-31, Page 15, lines 1-32; '969 Patent, Column 7, lines 30-68, Column 8, lines 1-10). Evening primrose oil is a source of linolic and linolenic acid (Page 4, lines 1-21; '969 Patent, Column 2, lines 26-48). Examiner notes that US 6,471,969 is the 371 of WO 07/04668. The claims do not require the presence of the plant or marine source only the essential fatty acid. The process by which the essential fatty acid is procured, i.e. derivation from the plant source or a marine source does not patentably distinguish the claimed product from the prior art. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The Applicant argues that the prior art product requires the use of essential fatty acids in product A and product B based on claim 1 of the '969 patent. However, claim 1 of the '969 patent does not even require that either product A or Product B contain an essential fatty acid. The language of said claim clearly indicates that unsaturated fatty acids are one of a list of several ingredients that are to be selected but the claim does not require that unsaturated fatty acids must be selected. In any case, the claimed invention does not exclude essential fatty acids from being included in the dosage form containing the calcium.

The Applicant argues that the Applicant's clearly intend the dosage forms to be ingested at the same time. The Applicant fails to point out any disclosure in the Specification that provides support for this intention and the claims do not contain any language relative to administration. As such, the claims do not exclude separate administration of the dosage forms. In any case, even if the claims contained said language, the intended use of a composition does not patentably distinguish the claimed invention absent evidence that the intended use adds a structural difference between the prior art product and the claimed product or evidence that the dosage forms in the nutritional supplement disclosed in the prior art cannot be administered at the same time, regardless of whether the prior art discloses or suggests that they are intended to be administered separately. See, e.g., In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure

is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)).

Further, the prior art discloses that the administration in capsule A is preferably administered in the morning and the capsule B is preferably administered in the evening (US '969, Column 7, lines 15-33). As such, the prior art reference does not require that the capsules be administered at different times, only that it is preferred that they are administered at different times. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). As such, the prior art does not teach away from the claimed invention.

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/04668.

WO 97/04668 discloses a nutritional supplement which a soft gelatin capsule A contains evening primrose oil and soft gelatin capsule B contains calcium falling within the scope of applicant's claims (Page 14, lines 20-31, Page 15, lines 1-32; '969 Patent, Column 7, lines 30-68, Column 8, lines 1-10). Evening primrose oil is a source of linolic and linolenic acid (Page 4, lines 1-21; '969 Patent, Column 2, lines 26-48). WO 07/04668 discloses that various amounts of trace elements and minerals, such as, such as calcium in the form of an inorganic, such as calcium carbonate, or an organic compound can be contained in the soft gelatin capsules (Pg. 7,

lines 21-29, Pg. 8, lines 1-5, 15-31, Pg. 10, lines 34-37, Pg. 11, lines 1-15, Pg. 13, lines 10-25). Examiner notes that US 6,471,969 is the 371 of WO 07/04668.

The prior art discloses a nutritional supplement in which a capsule A includes in the ingredients, essential fatty acids and does not include calcium and capsule B, which includes calcium. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the specified amounts of calcium. However, the prior art amply suggests the same as the prior art discloses the preparation of soft gelatin capsule containing various amounts of calcium. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior as above with the expectation that the amount of calcium could be varied as desired depending on calcium supplementation desired.

The examiner notes that the Applicant does not appear to have addressed this rejection. The arguments appear to be directed to the 102/103 inherency rejection of claims 23-28 above. The obviousness rejection herein rejects all pending claims 23-30 not just claims 23-28. In any case, the arguments would not overcome the rejection herein. As indicated above, the prior art does not exclude ingesting at the same time. The claimed invention does not require ingestion at the same time. As such, the prior art does not teach away from the claimed invention.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

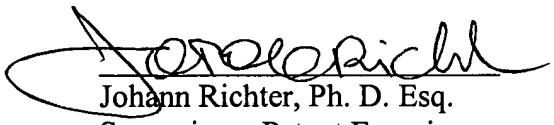
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
September 24, 2006



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